DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 25 2002

Generi Tech Corp
Attn: Norma D. Daliva-Banks
4967 East Lansing Way
Fresno, California 93727

Re: Docket No. 98N-0337
Comment Nos. APP15, APP16, and APP32.

Dear Ms. Daliva-Banks:

This is in response to the letters dated March 8, 2001, March 23, 2001, and October 29, 2001, from Robert Riedl, Thursday Plantation Laboratories Limited, requesting an exemption from certain provisions of the labeling requirements for over-the counter (OTC) drug products (21 CFR 201.66) for "Thursday Plantation 100% Pure Tea Tree Oil," 0.5, 1, and 2 fl. oz. sizes (APP15), a 1/3 fl. oz. size (APP16); and a 1.69 fl. oz. size (APP32).

The basis for the request is that the label sizes are too small to fit bar lines and all the wording in the font size required.

The March 8, 2001 letter contains two labels for each 0.5, 1, and 2 fl. oz. size products. The letter states that one label is in the required font size and one label is enlarged by 200%. The March 23, 2001 letter contains proposed labeling for the 1/3 fl. oz. size product. Subsequently, in a fax of June 29, 2001, you provided labeling for the 1/3 and 2 fl. oz. sizes of the currently marketed products with the type size of the fonts identified. We note that the type size for the currently marketed 1/3 fl. oz. product is less than 6.0 point, the minimum size required by 21 CFR 201.66. The fax also indicates that the product will be marketed to the consumer in the immediate container and that no outer carton or container will be used. The October letter contains labeling for the 1.69 fl. oz. product. We note that the labeling for this size package was not submitted in "Drug Facts" format like the proposed labeling submitted on March 8, 2001.

We have reviewed the Thursday Plantation request and have the following comments:

1. Mr. Riedl's letter recognizes that a decrease in type size will cause deterioration of the text legibility. We agree that a reduction in type size is not an acceptable option. We are unable to read the labels, even for the 2 fl. oz. product. As a result, we used the label that was enlarged by 200%. The difficulty in reading the label may have been caused by print bleeding resulting from copying the

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label. However, the label for the marketed product must be legible and in the type size (no smaller than 6 point type) required by the regulation.

2. We note that the "Drug Facts" label contains information in the drug facts box that need not be there. For example, all of the information except "store at room temperature" is not required in the "Other Information" section of the "Drug Facts" label and should be placed elsewhere in the labeling as desired.

3. The use of less than 6.0 point (5.3 point) for the type size of the fonts for the 1/3 fl. oz. product is not acceptable.

As discussed in the OTC labeling final rule (64 FR 13254 at 13267 and 13268, copy enclosed), products that are unable to meet the labeling format described in 21 CFR 201.66(d)(1) through (d)(9) or the modified format authorized under 21 CFR 201.66(d)(10) will be expected to be reconfigured to meet the formal requirements of the OTC labeling regulations. The analysis of impacts discussion in the final rule contemplated the cost of redesigning a product label, if necessary. The agency stated that it will not routinely grant exemptions or deferrals, particularly for print size, under 21 CFR 201.66(e) for packages that claim to be too small to meet the labeling requirements of the final rule. Manufacturers seeking an exemption on the basis of limited labeling space should include specific information detailing their efforts to comply with the rule by increasing available label space or package size. A number of labeling options are available (see p.13268 enclosed).

The agency reiterated its position in a February 4, 2000 response to a citizen petition, submitted on behalf of the Consumer Healthcare Products Association (CHPA). In that letter (copy of pertinent part enclosed), the agency discussed in detail why type size smaller than 6 point will not be allowed for products using the modified labeling format. Further, the agency explained that it is unlikely to grant exemptions based solely on financial considerations. The final rule has already addressed the fact that there will be increased costs to some manufacturers to comply with the new labeling requirements and that some products will need to be repackaged or may disappear from the market. While FDA is not likely to grant exemptions based on the limits of existing packaging to accommodate the required content and format, the agency will consider requests for additional time to allow manufacturers to change over to a larger or alternative package style.

There is currently no final monograph for OTC first aid antiseptic drug products, and therefore, you are not required to convert the labeling of Tea Tree Oil products to the new format at this time. You must comply with the requirements of 21 CFR 201.66 at the time that the monograph becomes final. However, if the monograph has not been finalized by May 16, 2002, then your product must comply with 21 CFR 201.66 as of the first major labeling revision after May 16, 2002 (see the Federal Register of June 20, 2000 (65 FR 38 191)) or by May 16, 2005, whichever occurs first.

If you have any questions, please contact Babette Merritt, Regulatory Health Project Manager, at 301-827-2222.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosures

under NDA's and ANDA's. The agency therefore has incorporated into this final rule a requirement that a table be used when dosing information is complex, as when separate dosing instructions are presented for three or more age groups. A text format may be used when there are less than three dosage directions.

10. Small Packages (§ 201.66(d)(10))

Section 201.66(d)(10) establishes a modified labeling format for packages that cannot meet the format requirements of paragraphs (d)(1) through (d)(9).

31. Several comments urged the agency to adopt a broad, blanket small package exemption from the proposed content and format requirements. The comments described small packages as those products that are marketed in unit doses, convenience sizes, samples, minimal net content packages, analgesic products with less than 6 square inches of usable labeling space, uniquely shaped containers (e.g., envelope packaging, which has a front and back panel only), tubes, roll packs commonly used for antacids, some ophthalmic products, a number of drug-cosmetic products, and bottles without an outer carton.

Many comments suggested graphical flexibility to accommodate products marketed in small packages, such as: (1) Use of more than one panel, (2) use of sans serif fonts or more than one font, (3) reduced type size (to 4.5-point), (4) reduced or no leading, (5) interlined spacing such that one line's ascenders do not touch the preceding line's descenders, (6) eliminate hairlines and required bullet spacing, and (7) consolidate warning information. One comment suggested that graduated type size requirements could be adopted depending on the available label space and cited the dietary supplement labeling provisions in § 101.36(c)(6) (amended and recodified at § 101.36(i), effective March 23, 1999 (62 FR 49826, September 23, 1997)). Another comment pointed out that the dietary supplement labeling provisions allow a minimum 4.5-point type size.

Some comments contended that relying on a subjective standard to support an exemption would be inefficient. These comments recommended that a small package be defined as any outer package: (1) Where the total surface area available to bear labeling is less than 12 square inches (including the PDP); or (2) where more than 60 percent of the total surface area available for labeling on the back and side panels must be used to satisfy the "content requirements" in proposed § 201.66(c); or (3) that is a trial size package, packet, or single use unit. Some comments proposed that any drug or drug-cosmetic product that meets this definition be exempt from the new format and content requirements, but should still bear all required labeling. Some comments stated that a performance standard, as described in the proposed rule (62 FR 9024 at 9036), has not been established or validated and would be impractical to use for small packages at this time.

The agency agrees that some manufacturers may have difficulty providing important drug information, which is prominent and easy to read, on packages that are irregular (i.e., bottle labels) or small (i.e., unit does). However, the agency also considers the required OTC drug labeling information essential for the safe and effective use of OTC drug products, irrespective of the size or the shape of the package.

Because readability is especially dependent on vertical letter height and letter compression, the agency disagrees that less than 6-point type or letter compression allowing more than 39 characters per inch should be permitted (Ref. 11), even on "small packages." As discussed in response to comment 23 in section IV.D of this document, the agency considers 6.0 type the minimum allowable for OTC drug product labeling.

The agency, however, is including in § 201.66(d)(10) of this final rule several modifications that may be used with packages that are too small to meet the format requirements of paragraphs (d)(1) through (d)(9). Under § 201.66(d)(10), headings may be presented in a minimum 7-point or greater type size. The leading may be adjusted so that the ascenders and descenders of the letters do not touch, rather than the 0.5-point leading required under § 201.66(d)(3). Also, bulleted statements may continue to the next line of text and need not be vertically aligned. Finally, the box or similar enclosure required in § 201.66(d)(8) may be omitted if the headings, subheadings, and information in § 201.66(c)(1) through (c)(9) are set off from the rest of the label by color contrast.

As suggested by the comments, a product will be considered "small," and will be permitted to apply these modifications, if more than 60 percent of the total surface area available to bear labeling on the entire outside container or wrapper, or the immediate container label if there is no outside container or wrapper, would be needed to present FDA required labeling. This consists of the labeling required by § 201.66(c)(1) through (c)(9), in accordance with the minimum specifications in § 201.66(d)(1) through (d)(9) and any other FDA required information for drug products and, as appropriate, cosmetic products, other than information required to appear on a principle display panel. This formula is consistent with the idea that 40 percent of available labeling space is generally reserved for the UPC symbol and PDP (see, e.g., 21 CFR 101.1 and § 201.60 (21 CFR 201.60)).

In determining whether more than 60 percent of the available surface area is needed, the indications listed under the "Use(s)" heading must be limited to the minimum required uses allowed under the applicable monograph. Also, for purposes of this rule, the "total surface area available to bear labeling" does not include the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars. All other surface areas are considered to be "available to bear labeling."

32. Several comments stated that the format under the proposed rule would require manufacturers to increase the package or container size of a significant number of OTC drug products. NDMA, for example, reported that a survey of its members showed 33 percent of branded products and 95 percent of private label products could not comply with the proposed format without making some change in package or container size. Some comments also opposed the mandatory use of alternative packaging designs, such as extending a single side panel of a package to increase labeling space, as had been suggested by the agency in the proposed rule (62 FR 9024 at 9036). According to these comments, the cost of adding such packaging features, and the additional environmental waste associated with increasing package size or configuration, outweighs the need to set a minimum 6.0 type size and other minimum format requirements. Several comments made general reference to state "slack fill" laws, which prohibit the use of oversized containers to mislead consumers.

Other comments, however, encouraged the use of alternative packaging to ensure that important information is presented in a readable type size with user-friendly visual cues. They emphasized that consumers need the information, and need to be able to read and understand the information, for proper self-selection and self-medication, and that these concerns support the required use of alternative packaging to increase available labeling space.

As discussed in section VIII of this document, the comments that oppose the required use of alternative packaging

design greatly overestimated the number of products that would not be able to accommodate the proposed format within the confines of current packaging. In addition, the modified format authorized under § 201.66(d)(10) of the final rule is expected to enable many small package products to comply without increasing container or package size.

For those remaining products that are unable to accommodate the modified, small package format, a number of design techniques are available to increase labeling space. As suggested in the proposed rule, labeling space can be increased by, for example, extending a single side panel or widening the label affixed to a bottled drug product (62 FR 9024 at 9036). In a survey described in section VIII of this document, the agency found that many products are now marketed with extended panels, peel back or fold out labels, or are otherwise mounted on cardboard cards or placards. These alternative packaging techniques often increase labeling space for promoting the sale of the product and could also be used to accommodate FDA required information. The agency likewise expects that any packaging changes needed to conform to this rule will be sufficiently minimal, and can be done in a manner, as to not render the product misleading under a "slack fill" law or similar provision (see, e.g., section 502(i)(1) of the act).

Thus, products that are unable to meet the labeling format described in § 201.66(d)(1) through (d)(9), or the modified format authorized under § 201.66(d)(10), will be expected to be reconfigured to meet the format requirements of this rule. The agency will not routinely grant exemptions or deferrals under § 201.66(e) for products that claim to be too small to meet the requirements of this rule.

Finally, the agency is not requiring manufacturers to increase the size of immediate containers (for those products that are marketed with outside retail packages) in order for the required format to be applied to the immediate container (see 62 FR 9024 at 9037). As stated in response to comment 3 in section IV.C of this document, for products that are sold with an outer package, the agency is encouraging, but not requiring, the use of the modified, small package format in § 201.66(d)(10) on the immediate container.

E. Exemptions and Deferrals (§ 201.66(e))

Proposed § 201.66(e) provided that the required labeling information must be the first information that appears on the back or side panel of the outside container or wrapper of the retail package (or the immediate container label if there is no outside container or wrapper) of all marketed OTC drug products. As explained in the following paragraphs, the agency has eliminated this requirement to give manufacturers more flexibility. In addition, the agency has codified proposed § 201.66(f), Exemptions and deferrals, as § 201.66(e) and has made several changes to make the exemption process less burdensome on manufacturers and on the agency.

33. Several comments recommended that the agency allow the inclusion of a brand name and product attributes anywhere on the information panel as long as they do not interrupt the flow of the required information and as long as the labeling is in compliance with the type size requirements. Several comments requested that the product brand name be the first text allowed on the information panel and that the equivalent of three lines of type be allocated at the top of the panel for a brand name and product attributes such as: (1) Information about dosage form, flavor, the absence of certain ingredients, directions for opening the package, and reference to the importance and benefits of proper use; (2) references to alternative products that are available; and (3) information from organizations endorsing the product. Other comments raised concerns about whether adequate space would be allowed for guarantee statements, signage, and sell copy. Another comment suggested that the space for a brand name and product attributes should be equivalent to the greater of either: (1) Three lines of the minimum size copy across the width of the information panel; or (2) 10 percent of the main information panel, at the option of the manufacturer. The comments maintained that this information is important to consumers for comparative purposes and for identification of products with desired features.

The agency has determined that the required OTC drug product labeling information need not appear as the first information on the back or side panel, provided there is adequate space on the outside container or wrapper for the labeling to conform with § 201.66(c)(1) through (c)(9) and § 201.66(d)(1) through (d)(10). Accordingly, the agency is not including proposed § 201.66(e) in this final monograph. Thus, a brand name and product attributes may appear anywhere on the labeling outside of the boxed area.

34. A number of comments suggested that FDA establish an exemption process other than a citizen petition. The comments contended that the petition process is too slow and burdensome for both industry and the agency, and would cause marketing delays. Some comments suggested a simple notification process when a company is unable to comply with the final rule. The company would notify the agency, a certain time would be allowed for the agency to respond with any objections, and, if no objections were provided, marketing could then proceed.

Section 201.66(e) in this final rule provides that FDA, on its own initiative, or in response to a written request from any manufacturer, packer, or distributor, may exempt or defer, based on the particular circumstances presented, one or more specific requirements set forth in § 201.66(a) through (d), on the basis that the requirement is inapplicable, impracticable, or would be contrary to public health or safety.

The agency agrees that the exemption process need not require a citizen petition. However, the process should be a matter of public record and requests for exemptions must be granted by the agency prior to marketing. Requests for exemptions must be submitted in three copies in the form of an "Application for Exemption" to the agency. The requests shall be clearly identified on the envelope as a "Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)" and with Docket No. 98N-0337. A separate request must be submitted for each OTC drug product. In addition to the three copies of the exemption request submitted to the agency, manufacturers of a product marketed under an approved drug application must also submit a single copy of the exemption request to their application. Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review.

The request for exemption or deferral must: (1) Document why a particular requirement is inapplicable, impracticable, or would be contrary to public health or safety, and (2) include a representation of the proposed label and labeling, including outserts, panel extensions, or other graphical or packaging intended to be used with the product.

35. In the proposed rule, the agency asked for comment on whether there are particular types of products or packages that should be granted a regulatory exemption (62 FR 9024 at 9038). At least one comment, from a trade association, requested that "drug-cosmetic products," and particularly those that do not have a dosage limitation (e.g., antidandruff shampoos, anticaries

amended to allow more ways to use columns, would be to file a petition under 21 CFR 10.25(a).

B. Trade Dress

The agency believes the technical amendment document, published on January 3, 2000 (65 FR 7), resolves the questions that CHPA and others raised, following publication of the final rule, about the use of certain light on dark combinations of print. Therefore, an extension of the primary implementation date is not needed to allow for further discussion of this issue.

C. Type Size

The final rule requires a minimum type size of 6 points when presenting information in the "Drug Facts" labeling. 21 CFR 201.66(d)(2); *see generally* 64 FR at 13264-65. Since publication of the rule, CHPA has made several presentations on the issue of type size. CHPA estimates that as many as 30 percent of OTC stock keeping units cannot comply with the rule, and that type size is the most significant factor in determining whether the new labeling will fit onto an existing package.

Accordingly, CHPA has asked the agency to delay implementation of the rule to consider the use of smaller type sizes, especially for small packages. CHPA has argued that data in the record support a minimum type size of 4.5 points. Also, CHPA insists the agency lacks an adequate basis to require a 6 point minimum. Finally, CHPA has continued to raise the need for "type size parity" across all FDA regulated products. *See, e.g.*, Ex. 1; Ex. 2 at 6, slide 12. For the reasons discussed below, the agency does not agree that additional time is needed to consider type size issues.

1. General Factors

FDA has been considering the issue of type size for OTC drug products since at least 1990, when the Pharmacists Planning Service (PPS) petitioned FDA to set minimum standards for OTC drug labeling. Among other things, the petition emphasized that significant numbers of older adults have been hospitalized due to adverse drug reactions involving OTC drugs, and that most people (especially the elderly) are unable to read the print on OTC drug labeling. 62 FR at

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comments to the proposed rule, columns were listed as one many factors that may affect readability. The agency, however, found no substantive discussion by CHPA of the use of columns or the idea of allowing information under certain headings to be divided into columns ("columns within columns"). None of the labels appended to CHPA's comments, in which CHPA suggested modifications to FDA's proposed format, shows the use of "columns within columns." *See* CHPA comments, App. E. The "Recommended Format" submitted by CHPA with its comments, App. F, does not show or suggest the use of columns.

9028.

The issue of assuring readability for elderly consumers has been a significant consideration throughout this process. Although the elderly comprise 12 to 17 percent of the population, they consume about 30-50 percent of all drug products. 62 FR 9024, 9027. As discussed in a 1994 study, a significant number of elderly consumers (60 yrs or older) could not adequately see the print on certain OTC product labels due in part to small type sizes and horizontal letter compression. *See* 62 FR at 9028 (*citing* Ex. 3); *see also* Sept. 29, 1995, Public Hearing on Over-the-Counter Drug Labeling Transcript at 31, FDA Docket No. 95N-0259 (hereafter Transcript) ("[T]he elderly are more likely to use over-the-counter medications, more likely to have a higher incidence of medical conditions that may be adversely affected by the inappropriate use of medications, and more likely to be taking other medications that may have adverse interactions with certain over-the-counter medications.").

Second, the goal of this proceeding has been to set standards for clear, consistent, easy-to-read drug labeling, and to minimize the "cognitive load" that drug labeling places on lay consumers. *See, e.g.*, 64 FR at 12355. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act, drug labeling must be sufficiently prominent and conspicuous "as to render it *likely to be read and understood* by the ordinary individual . . ." 21 U.S.C. 352(c) (emphasis added); *see* 64 FR 9043. Marginal type sizes, or type sizes that are legible only at threshold levels, make it *less likely* that a consumer will begin to read the labeling, let alone read it thoroughly.

Third, as discussed below, the agency carefully considered industry practices in setting a minimum type size for OTC drug labeling, to help ensure the adoption of an attainable standard.

2. CHPA's Approach

CHPA's central study in support of the argument that 4.5 point type is an appropriate minimum standard for OTC drug labeling is Sidney Smith's 1979 article, "Letter Size and Legibility" (attached as Ex. 4).[4]

Smith studied "display legibility" using a variety of test materials, none of which appears to have included drug labeling. Ex. 4 at 665. Some of Smith's samples consisted only of a single word. *Id.* at 667. Moreover, the subjects in the study were asked only to identify the

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[4]CHPA referenced the Smith study in its comments to the proposed rule (*see* CHPA comments to proposed rule, App. H.) and in correspondence with the agency prior to the proposed rule. *See, e.g.*, Ex. 5. Although Smith and the other studies discussed in this section are already part of the record of this proceeding, the agency them as exhibits to this response, for the convenience of the reader.

absolute "legibility limit" for a given piece of display material. *Id.* at 666 ("The only measure taken was the legibility limit."). Viewers were not asked to specify a comfortable or preferred viewing distance, nor were they asked to identify the distance from which the material could be read with ease. Also, Smith did not record the age of his test subjects. There is even some suggestion that most may have been under 30 years of age. *Id.* at 668.

In contrast, the focus of this proceeding has been on labeling that consumers are *likely* to read and understand, from beginning to end, rather than on the threshold levels at which consumers can first begin to see printed material. *See* 21 U.S.C. 352(c). There is an important distinction between what a consumer is able to see, and what a consumer is likely to try to read – from beginning to end, with minimal error. As Smith cautioned:

> In practical display applications, however, it is not wise to design to the limits of visual acuity. An engineer will not design a bridge to meet minimum loads, but instead multiplies the strength of supporting trusses by some safety factor so that the bridge can be crossed with greater confidence. A display designer should also include some safety margin, specifying a letter size large enough to be read with confidence.

Ex. 4 at 662 (emphasis added).

Finally, following publication of the final rule, CHPA has continued to reference Smith for the idea that "98% of test subjects could read 4.5 point type at a distance of 13 inches." Ex. 6 at 7. In fact, Smith found that 98 percent of his test subjects could read copy that subtended a visual angle of 0.0046 radians.

According to CHPA, a visual angle of 0.0046 radians corresponds to a letter height of 0.06 inches at a viewing distance 13 inches,[5] and a letter height of 0.06 inches corresponds to a point size of 4.5. Ex. 5 at 2. However, a type size of about 6 to 8 points would be needed to present text that is generally 0.06 inches in height. This is because, as CHPA has stated, letters set in 4.5 point type are *not* 0.06 inches high.[6] *Id.* CHPA's submissions to the agency state that point size is a measure of the total height from the bottom of the lowest letter to the top of the highest letter, and that the upper case letters in 4.5 point type are usually only .042 inches or about 3 points. *Id.* Lower case letters in 4.5 point type would be even smaller – about half the

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[5]Although CHPA assumes a viewing distance of 13 inches, other materials cited by CHPA suggest 16 inches as the appropriate benchmark for "reading distance." Ex. 5 at 3 (citing Holt, G., *et al..*, "OTC Labels: Can Consumers Read and Understand Them?" 11 *American Pharmacy* 51 (Nov. 1990)). Using 16 inches, the letter height would be 0.0736 inches.

[6]Type sizes are designated in units called points. There are approximately 72 points to one inch. Each point measures 0.0138 of an inch.

point size or 0.03 inches. Therefore, to achieve the level of legibility that CHPA relies on from the Smith study, one would need to use text that is more than 6 points (assuming a viewing distance of 13 inches and the use of all upper case letters); or 8 points (assuming a viewing distance of 13 inches and the use of primarily lower case letters)[7]. Added to that, Smith found that letter sizes intended for close viewing, such as consumer labeling, may need to be larger in size than one would derive from a measure of the limits of visual acuity. *Id.* at 668.[8]

For these reasons, the agency disagrees with CHPA that the Smith study supports the use of 4.5 point type in OTC drug labeling. Indeed, Smith would support the use of a larger type size (6 point *or greater*) for consumer-directed drug labeling.

CHPA has also directed the agency to "the definition of visual acuity" to support the use of 4.5 point type in OTC drug labeling. *See, e.g.*, Ex. 5; Ex. 7. According to CHPA, a person with 20/20 vision can read text 0.019 inches high at a distance of 13 inches (equal to 1.7 point type), a person with 20/40 vision can read text 0.037 inches high (equal to 3.3 point type), and a person with 20/55 vision, according to CHPA, would be able to read 4.5 point type. *See* Ex. 5 at 3; *see also* Ex. 7 at 1.

For reference, the following sentences are set in 1.7, 3.3, and 4.5 point type:[9]

This sentence is in 4.5 point Times New Roman type

Each of these type sizes – if one accepts CHPA's assumptions – represents the threshold limit at which a person with a given visual acuity can begin to see text. They do not represent type sizes which can be read with ease. *See* Ex. 4 at 662 ("Design standards for visual displays generally

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[7]The OTC labeling rule requires primarily the use of *lower case* letters. *See* 21 CFR 201.66(d)(1).

[8]Smith also found that 100 percent of his subjects could read a letter size of 0.007 radians. *Id.* at 667. Using CHPA's method of converting this figure to a point size, Smith found that 100 percent of his test subjects were able to read 6.6 type at a distance of 13 inches. If one adjusts for the use primarily of lower case letters and a viewing distance of 16 inches, one would need to use a type size of more than 12 points to attain the level of legibility found by Smith.

[9]The following sentences are set in 6, 8, and 10 point type:

This sentence is in 6 point Times New Roman type.

This sentence is in 8 point Times New Roman type.

This sentence is in 10 point Times New Roman type.

recognize the need for a safety margin, and specify letter sizes larger than those at the limits of visual acuity."). Moreover, if one adjusts for a standard reading distance of 16 inches, and takes into account the use of primarily lower case text, each of these types sizes would have to be adjusted *upward*. The agency also notes that type size is only one factor that determines readability (*see* 62 FR at 9028), and that OTC labeling – which often consists of extensive and complex text – can be especially demanding for the reader.[10]

At best, CHPA's approach may help to establish a base from which to develop specific minimum type sizes for specific categories of products. As discussed below, the agency has allowed the use of the smallest readable type size in certain contexts (*see* section II.C.4, below). For OTC drug labeling, however, there is ample basis to require a larger size.

3. The Industry Standard

A key starting point for FDA in setting an appropriate minimum type size for OTC drug labeling was to consider current industry practice. At the agency's September 1995 public hearing, CHPA testified that most of the OTC drug industry had already adopted 6 points "*or better*" as the standard:

> We have done a label survey of our members looking at 2,000 labels and over 95 percent were at six point or better, and I think one of the practicalities is that there is a huge amount of information that is required on some of these labels. The particular diphenhydramine prototype that is in Appendix C [is] done at around six points, if you do that at seven points [it] will not fit the package. So, we recommend adopting the current industry practice."

Transcript at 108 (emphasis added).[11]

The agency, in turn, incorporated the industry standard into the OTC labeling rule after hearing additional testimony and after reviewing several studies confirming the readability of 6

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[10]In contrast, a study submitted by the American Pharmaceutical Association with a comment to the proposed rule evaluated the readability of 9 OTC drug labels with type sizes ranging from 4 to 11 points. Ex. 8. The study found that subjects needed at least 20/30 vision to read OTC drug labeling in 4 point type and 20/40 vision to read labeling in 6 point type. Only one of the labels (presumably, a label set in 11 point type) could be read accurately by those with a visual acuity of 20/50. Ex. 8 at 51.

[11]In its written submission to the public hearing, CHPA noted that "as an absolute minimum, 4.5 print type is reasonable for OTC labels, though not often used. Six point type is commonly used and preferred." Ex. 9 at 17.

point type for OTC drug products. For example, the National Consumers League (NCL) testified at the September 1995 hearing on an "investigative survey" of OTC drug labeling. In the study, 60 adults were asked to assess the readability of OTC products ranging in size from 4.0 to 6.5 point type. Ex. 10 at 3. As the agency noted in the rulemaking, NCL found that only 32 percent of the subjects age 51 and older were able to read OTC drug labeling set in 4.5 point type. 64 FR at 13265. Among the labels tested by NCL, the one set in 6.5 point type proved best, with 75 percent of the subjects age 51 and older, and 94 percent of the subjects under age 51, able to read it. On the other end of the spectrum, none of the subjects age 51 and older was able to read one of the labels set in 4 point type, and only 25 percent of the subjects under age 51 were able to read the label. Ex. 10 at 8. Thus, the NCL survey raises concerns about the readability of type sizes around a 4.5 point range and, at the same time, supports the use of type sizes in the 6.5 point range.[12]

The Watanabe study, cited by the agency in the rulemaking, also supports the use of a 6 point or better type size. Dr. Watanabe sampled 92 consumers, 60 years of age and older, using three labels – two set in 3.3 point type and one set on 6.7 point type. Ex. 3 at 33; *see also* 64 FR at 13265. In addition to showing that horizontal letter compression is a significant factor in determining readability, the Watanabe study concluded that a vertical type size of at least 6.7 points should be used in OTC drug labeling.[13]

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[12]At the November 23, 1999, feedback meeting, CHPA stated that the NCL study supported the use of less than 6 point type. Ex. 2 at 6, slide 11. The 5 point label tested in the NCL survey performed at the same level as one of the labels set in 6 point type. Forty-eight percent of the subjects age 51 and older either could not see the text on either label or found it too hard to read. Factors, such as color contrast, layout, or letter compression, may have accounted for these results. However, a second label tested by NCL, set in 6 point reverse type significantly outperformed the other labels. Sixty-eight percent of the older subjects and 91 percent of the younger subjects were able to read it. Ex. 10 at 9.

[13]At the November 23, 1999, feedback meeting, CHPA asserted that the Watanabe study "showed little difference in readability between 6.7 and 3.3 point type." Ex. 2 at 6, slide 11. We disagree. In a comparison of one of the 3.3 point labels to the 6.7 point label, Dr. Watanabe found that approximately 30 percent of the subjects were unable to either start *or finish* reading the 3.3 point label. Only 2 percent were unable to read the 6.7 point label. In a comparison of the other 3.3 point label with the 6.7 point label, Dr. Watanabe found only a small statistical difference in readability, concluding that the horizontal letter compression on the 3.3 point label compensated significantly for the smaller type size. However, Dr. Watanabe also concluded that "subjective observations by both subjects and researchers indicate that greater effort was expended in reading the smaller print [on this label]," and that "[t]his suggests that letter size approximating the [6.7 point type size] should be used." Ex. 3 at 35.

The agency also received numerous comments from consumers, consumer groups, and health professionals in favor of adopting 6 point or larger as the minimum standard. *See, e.g.*, FDA Docket No. 96N-0420, C103; C104; C467. Consumer preferences and comments are significant in this proceeding, given the statutory directive to develop labeling that consumers will be "*likely*" to read.

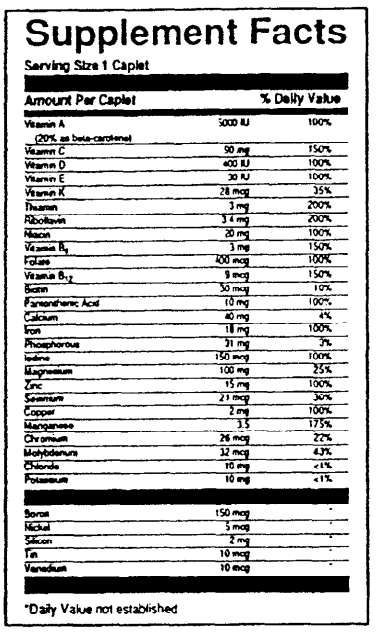
4. "Parity"

Finally, at the November 23, 1999, feedback meeting and at several other public meetings following the final rule, CHPA has emphasized the need for "consistency and fairness across FDA regulated consumer products." As noted in comments to the proposed rule, the agency allows certain dietary supplement products to use a minimum 4.5 point type. 21 CFR 101.36(i). The agency has also allowed letters no less than 1/16th of an inch for the listing of ingredients in cosmetic products, or 1/32 of an inch in limited circumstances. 21 CFR 701.3(b) and (p).

The agency carefully considered this issue in the final rule and did not find it to be decisive. 64 FR at 13265. As the agency outlined in the rule, factors such as the nature and quantity of the information required, and the manner in which the information is presented, may allow for the use of different labeling specifications. In some contexts, there is often little required information presented on the labeling (either a few words or a single sentence), and there is adequate white space to enhance readability, putting less of a demand on the user to read the information.

This point is illustrated below. Figure 1 shows a multi-ingredient dietary supplement product with the required text presented in 4.5 point type, compared with a multi-ingredient OTC drug product. The OTC drug product follows the modified format permitted under 21 CFR 201.66(d)(10), except that for purposes of illustration the drug product uses 4.5 point type to present the required text rather than the required 6 point minimum. Figure 2 compares the multi-ingredient OTC drug product in 4.5 point type versus 6 point type. Figure 2 illustrates the benefit of a larger type size in OTC drug labeling. Both figures use optimal color contrast (black text on a non-glossy white background).

Figure 1

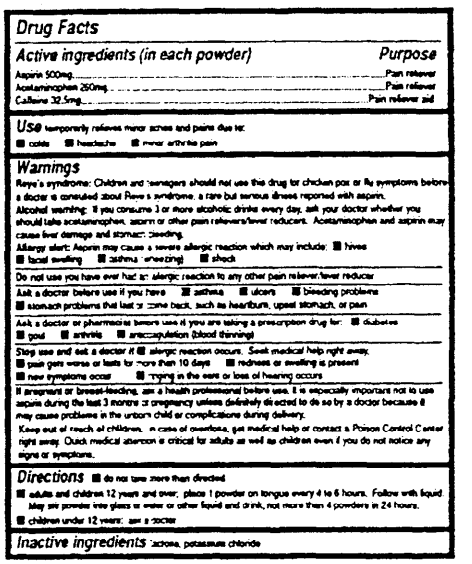


Supplement Facts

Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantothenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	26 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

*Daily Value not established



Drug Facts

Active ingredients (in each powder) — *Purpose*

Aspirin 500mg ..... Pain reliever
Acetaminophen 250mg ..... Pain reliever
Caffeine 32.5mg ..... Pain reliever aid

Use temporarily relieves minor aches and pains due to:
■ colds ■ headache ■ minor arthritis pain

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin.
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen, aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.
Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have ■ asthma ■ ulcers ■ bleeding problems ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ anticoagulation (blood thinning)

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

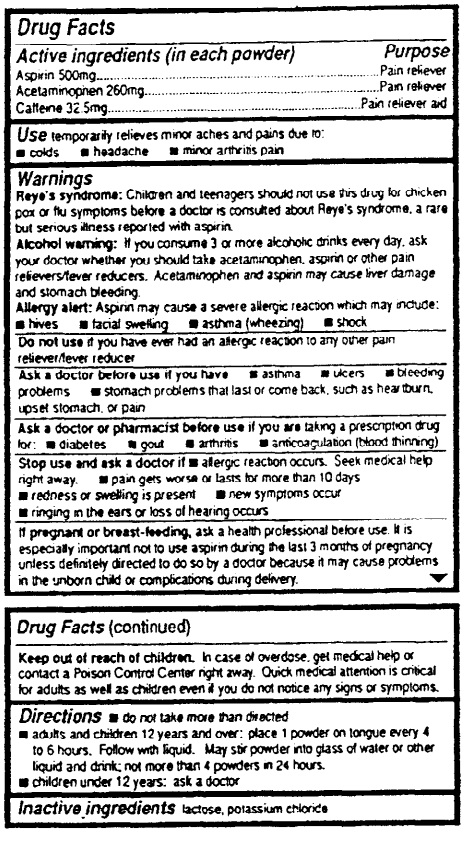
Directions ■ do not take more than directed
■ adults and children 12 years and over: place 1 powder on tongue every 4 to 6 hours. Follow with liquid. May mix powder into glass of water or other liquid and drink, not more than 4 powders in 24 hours.
■ children under 12 years: ask a doctor

Inactive ingredients lactose, potassium chloride

14 point Helvetica Regular Bold Title
6 point Helvetica Narrow Bold Headings
6 point Helvetica Narrow Subheadings
4.5 point Helvetica Narrow Text
5.5 point Leading

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

Figure 2



Drug Facts

Active ingredients (in each powder) — **Purpose**

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Acetaminophen 260mg — Pain reliever
Caffeine 32.5mg — Pain reliever aid

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Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin.

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Drug Facts (continued)

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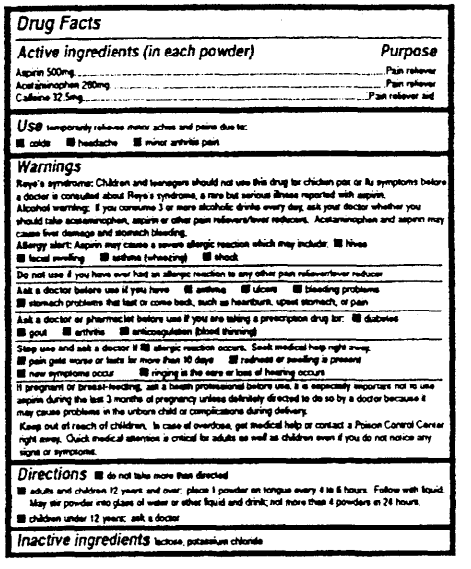

Drug Facts

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Inactive ingredients lactose, potassium chloride

9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6.5 point Leading

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

As the agency found in the final rule (and as illustrated here),.the overall "Supplement Facts" layout, including the tabular style and the limited amount of explanatory text, allows for the use of a smaller type size in limited circumstances.

The agency also notes that in other instances it has required 6 point or larger type. For example, the agency established a 10 point minimum type size for approved patient labeling for human prescription drug and biological products (*i.e.*, "Medication Guides"). 21 CFR 208.20(a)(4); *see also* 21 CFR 610.62 (requiring the use of 12 point and 18 point type when designating antibodies in certain biologic labeling). The minimum type size for food nutritional labeling for most products is 8 point type for certain information on the label and 6 point type for all other information. Small packages (less than 12 sq. inches) may opt not to present nutritional information. *See* 21 CFR 101.9(j)(13)(i). However, small packages that present nutrition information must use a minimum of 6 point type or all upper case letters of 1/16 inches in height. 21 CFR 101.9(j)(13)(i)(B).

Finally, for various warnings and other statements required on some FDA-regulated products, a type size or letter height of 1/16th of an inch has been required. *See, e.g.*, 21 CFR 101.93(e) ("letters of a type size no smaller than one-sixteenth inch"); 310.516(c)(1) ("minimum letter size shall be one-sixteenth of an inch in height . . . letter heights pertain to the lower-case letter 'o' or its equivalent that shall meet the minimum height standard"); 701.3(b) ("letters not less than 1/16 of an inch in height"); 740.2(a) ("in no case may the letters and/or numbers be less than 1/16 inch in height.").[14]

In short, the agency considered the labeling specifications for other product categories in developing the final OTC labeling rule. The agency also considered, however, the unique demands of OTC drug labeling, along with the strong trend in the OTC drug industry toward 6 point type, and determined that a type size larger than that allowed in limited circumstances for other categories of products such as dietary supplements was justified and reasonable.

* * *

The agency has carefully reviewed the issue of type size, including the points and materials CHPA highlighted in comments to the proposed rule and in correspondence and feedback meetings over the last several months. The agency concludes that there is no need to delay implementation of the rule to continue to consider this issue.

D. Single Use Packages, Convenience Packages, and Extended Text Labeling

The petition states that additional time is needed to resolve the labeling of single use and

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[14]Applying the analysis discussed in section C.2 of this response, if the minimum letter size permitted is 1/16 of an inch, a type size as large as 8 or 9 points may be needed in some instances to ensure that the smallest letter is no smaller than 1/16 of an inch. The limited instance in which the agency has allowed 1/32 inch type (21 CFR 701.3(p)) may require about 4.5 point type.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1-30-02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. APP15, APP16, APP32

Charles J. Ganley, M.D.

Attachment